

REMARKS

Claims 18-22 are pending in this application. No claims have been cancelled. No claims have been added. No claims have been amended.

Claims 18-22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Bergink '415 in view of Darney et al and Alapiessa et al. Applicants request that this rejection be withdrawn in view of the following remarks.

Claims 18-22 define a low-dose estrogen, triphasic desogestrel regimen that is neither taught nor suggested by the combination of references cited by the Examiner. With respect to Bergink, applicants note that this reference teaches a phasic contraceptive regimen in which the dosage of ethinyl estradiol (EE) is varied over the various phases. In particular, Bergink teaches a first phase in which the dosage of EE is 25 micrograms, and second and third phases in which the dosage of EE is lowered to 20 micrograms. This is in contrast to the present invention wherein the dosage of EE is kept constant at 25 micrograms over all three phases of the claimed regimen. Furthermore, as noted by the Examiner, Bergink teaches a 24 day cycle divided into three eight-day phases of hormone administration followed by a four day pill-free period or a four day period of progestin-only administration. Again, this is in contrast to the claimed regimen which includes 21 days of phasic hormone administration followed by a period which is free of hormone administration.

The Examiner argues that altering the active ingredient dosage level to effect optimal contraceptive benefit would be obvious based on the teachings of Darney. However, Darney teaches that cycle control increases and rates of breakthrough bleeding and spotting are reduced as the estrogen content increases. Darney teaches that cycle control is maximized with EE dosages of 30-35 µg or even a 50 µg. Darney goes even further when he recommends supplementing regular OC use with additional conjugated estrogen or estrone sulfate.

Accordingly, even if one skilled in the art were to combine Bergink and Darney as suggested by the Examiner, the result would be a phasic contraceptive providing an EE dosage substantially higher than that recited in the instant claims. Moreover, based on the

teachings of Bergink, the EE dosage would, itself, be phased at this much higher level, since Bergink teaches varying the EE dosage over the various phases of the regimen.

The Examiner argues that applicants have failed to provide data establishing the unexpected results achieved by the claimed invention. To this point, applicants direct the Examiner to the data contained in the tables and the examples set forth in the specification. These data show that good cycle control is maintained with a triphasic regimen utilizing a constant daily dosage of 25 micrograms of ethinyl estradiol. These results are completely unexpected in view of Darney's teaching that good cycle control is maximized where the daily dosage of estrogen is maintained at 30 to 50 micrograms. The good cycle control provided by applicants' low daily EE dosage is even more unexpected in view of Darney's suggestion that patients supplement regular OC use with additional conjugated estrogen or estrone sulfate.

The Examiner cites Alapiessa et al. for the teaching of a 21-day cycle. However, a person skilled in the art would not be motivated by the teachings of Alapiessa to alter the 24-day cycle taught by Bergink to the claimed 21-day regimen, since Alapiessa nowhere teaches or suggests a phasic contraceptive regimen wherein the EE dosage remains constant over the entire regimen while the progestin dosage is varied in discrete phases. Alapiessa teaches either monophasic regimens wherein the EE and progestin dosages remain constant over the entire regimen, or phasic regimens wherein there is an initial phase of estrogen-only administration followed by phase in which estrogen and progestin are administered together.

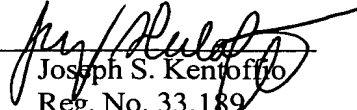
In view of the foregoing, applicants believe that claims 18-22 patentably distinguish over the cited art, and applicants request that a Notice of Allowance directed to these claims be issued at the earliest possible date.

Applicants do not believe that any fees are required in connection with the filing of this Response. However, should any fees be required, please charge Deposit Account No. 10-0750/ORT-1373/JSK.

Should the Examiner have any questions regarding this Response, please contact the undersigned attorney at the telephone number listed.

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Respectfully submitted,

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